

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION  
(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

United States Patent and Trademark  
Office  
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Crystal Plaza 2  
Washington, DC 20231  
ÉTATS-UNIS D'AMÉRIQUE

in its capacity as elected Office

Date of mailing:  22 October 1998 (22.10.98)	
International application No.:  PCT/EP98/02143	Applicant's or agent's file reference:  JAB 1267-PCT
International filing date:  07 April 1998 (07.04.98)	Priority date:  14 April 1997 (14.04.97)
Applicant:  EMBRECHTS, Roger, Carolus, Augusta et al	

1. The designated Office is hereby notified of its election made:

in the demand filed with the International preliminary Examining Authority on:

25 September 1998 (25.09.98)

in a notice effecting later election filed with the International Bureau on:

2. The election  was

was not

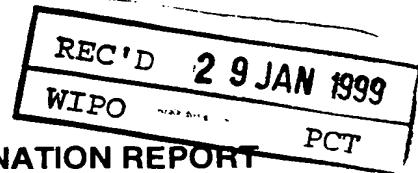
made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland  Facsimile No.: (41-22) 740.14.35	Authorized officer:  J. Zahra Telephone No.: (41-22) 338.83.38
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## PATENT COOPERATION TREATY

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## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>JAB 1267-PCT</b>	<b>FOR FURTHER ACTION</b>		See Notification of Transmittal of International Preliminary Examination Report (PCT/IPEA/416)
International application No. <b>PCT/EP98/02143</b>	International filing date (day/month/year) <b>07/04/1998</b>	Priority date (day/month/year) <b>14/04/1997</b>	
International Patent Classification (IPC) or national classification and IPC <b>A61K7/06</b>			
Applicant <b>JANSSEN PHARMACEUTICA N.V. et al.</b>			

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I     Basis of the report
- II     Priority
- III     Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV     Lack of unity of invention
- V     Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI     Certain documents cited
- VII     Certain defects in the international application
- VIII     Certain observations on the international application

Date of submission of the demand <b>25/09/1998</b>	Date of completion of this report <b>27.01.99</b>
Name and mailing address of the IPEA/ European Patent Office D-80298 Munich Tel. (+49-89) 2399-0, Tx: 523656 epmu d Fax: (+49-89) 2399-4465	Authorized officer  <b>Simon, F</b> Telephone No. (+49-89) 2399-2083



**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/EP98/02143

**I. Basis of the report**

1. This report has been drawn on the basis of (substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.):

**Description, pages:**

1-15 as originally filed

**Claims, No.:**

1-14 as originally filed

2. The amendments have resulted in the cancellation of:

the description,      pages:  
 the claims,           Nos.:  
 the drawings,        sheets:

3.  This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Yes:	Claims	1-14
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-14
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-14
	No:	Claims	

**INTERNATIONAL PRELIMINARY  
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2. Citations and explanations

**see separate sheet**

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/EP98/02143

*section V*

1. Reference is made to the following documents:

D1: GB 2 256 139 A (SANDOZ) 2 December 1992

D2: WO 96 29983 A (COLGATE-PALMOLIVE) 3 October 1996, cited in the application on page 1, line 25.

2. Novelty

The present application meets the requirements of Article 33(2) PCT, because the subject-matter of the independent claims 1 (composition) and 14 (process to prepare said composition) is not anticipated by the prior art mentioned in the search report.

D1 (see D1, claim 1) claims a detergent composition having a therapeutic effect on skin disorders comprising

- an anionic surfactant,
- an amphoteric surfactant, both surfactants combined specifically with each other,
- a therapeutic agent, e.g. ketoconazole.

D1 however does not disclose a composition containing a phospholipid.

D2 (see D2, claims 1 and 3) discloses a liposomal preparation containing:

- terbinafine as an antimycotic agent,
- a phospholipid.

D2 nevertheless neither discloses a composition suitable for cleansing the body or the hair nor a composition including art-known body or hair cleansing product ingredients. For example, the composition of D2 does not require surface active agents (see D2, page 2, §3) and all examples concern only pharmaceutical preparations, such as a liposomal gel (example 5) or a pulmonate application (example 6).

3. Inventive step

The present application includes an inventive step in the meaning of Article 33(2) PCT, because the subject-matter of the independent claims 1 and 14 is not

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

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obvious over the cited prior art.

D1 relates to mild skin care detergent compositions which exhibit a therapeutic effect in the treatment of skin disorders such as itching, irritation, skin dryness (see D1, page 1, lines 9-11 and page 2, lines 12-17). This kind of composition consequently can be equated with anti-dandruff shampoos (see D1, example 2). D1 is therefore considered as the closest prior art.

However, the invention of D1 is grounded on the discovery that use of a specific combination of anionic and amphoteric surfactants provides a mild surfactant base for a therapeutic aqueous, body cleansing composition, particularly in the form of a shampoo, such that the surfactant system does not tend to counteract or negate the therapeutic benefits afforded by the therapeutic agents present in the body cleansing composition or shampoo (see page 3, line 37- page 4, line 6). D1 does not suggest to the skilled man to combine the active ingredient ketoconazole with an amphoteric phospholipid.

D2 is devoted to the improvement of the bioavailability of terbinafine in a composition used to treat diseases caused by fungi. Even if an object of D2 is to reduce the side effects and the toxicity of such a composition, D2 does not deal with compositions against dandruff or seborrheic dermatitis (see D2, page 2, §2). A combination of the teaching of D1 and D2 would not lead the skilled person to a composition as claimed in the present application.